

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Bucolo et al.
Application No. : 10/812,551
Filed : March 29, 2004
Title : NEW FREE-RADICAL SCAVENGER CONTAINING
VISCOELASTIC COMPOSITION, METHODS OF USE AND
PACKAGE
Examiner : Benjamin J. Packard
Group/Art Unit : 1612
Conf. No. : 3392
Docket No. : P03491

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

Sir:

The Examiner has failed to make a *prima facie* case of obviousness.

"In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. The Examiner can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references."

In re Fritch, 972 F.2d 1260, 1265 (Fed. Cir. 1992)(citations omitted). In support of the alleged *prima facie* case, the examiner stands firmly on the statement that "when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious" and cites to *KSR International v. Teleflex*, 550 U.S. 398, 417, 127 S.Ct. 1727, 1740 (2007); Examiner's Answer (EA), page 5. Applicants dispute and reject the Examiner's approach that the mere identification of each component of a claimed composition without more is sufficient to establish a *prima facie* case of obviousness. The Court in KSR did not propose such a rigid,

bright-line rule for invalidating “combination” claims of novel chemical compositions. By adopting such a rule the Examiner commits legal error. Applicant Brief (AB), pages 11 and 12.

Applicants submit that the Court in *KSR* emphasizes “an expansive and flexible approach” to the obviousness question. *KSR*, 550 U.S. at 418. Specifically, with respect to combination patent claims the Court stated.

“[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, *it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.* This is so because inventions, in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some cases, is already known.”

Id. at 418-419 (emphasis added). Accordingly, one “must still be careful not to allow hindsight construction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention.” *Innogenetics, N.V. v Abbott Labs.*, 512 F.3d 1363, 1374 n.3 (Fed. Cir. 2008).

The Examiner does not provide a sufficient and substantiated reason as to why one of ordinary skill would combine the four recited components to form the claimed viscoelastic compositions. AB, page 14, top. For example, the Examiner does not explain in his Answer why one of ordinary skill in the art would select the specific four components and identify the claimed viscoelastic composition from the nearly 36,000 possible combinations of ophthalmic “eye drop” components listed separately or segmented as gums, optional mucoadhesive polymers, buffer and osmolality adjusting agents described by Singh. Again, the 36,000 permutations are derived only from these four separate segments of agents. Indeed, Singh lists

many more segments of compounds. In total, the total number of permutations of different ophthalmic compositions described in Singh is likely in the hundreds of thousands.

Yet, in spite of Singh's encyclopedic disclosure of ophthalmic agents, the Examiner maintains the position that it would have been obvious to one of skill to substitute hyaluronic acid for scleroglucam in Singh's Example ID21 and then rely upon the secondary references to fill in the remaining two components recited in the claims. In support of this reconstructive approach, the Examiner again relies upon an isolated statement by the *KSR* Court. "Addressing the issue of obviousness ...[one] 'need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take into account of the inferences and creative steps that a person of ordinary skill in the art would employ' ". EA, page 5. In this case, the creative steps would entail at the very least 36,000 creative steps. In this case, one is left with the definite conviction that the rejection can only be supported through the use of hindsight reconstruction of the prior art following a review of the application and claims. For this reason, Applicants respectfully request that the rejection of all the claims be reversed.

Applicants provide additional comments with respect to claims 26, 27 and 47. Claims 26 and 27 recite ranges of zero-shear viscosity and high-shear viscosity, respectively. Claims 47 recites a viscoelastic range of both zero-shear and high-shear.

With respect to these three claims, the Examiner does not address Applicant's argument that the term "viscoelastic" recited in the claims further defines the claimed compositions in terms of their viscoelastic properties. The Examiner conveniently ignores the term "viscoelastic" in the claims because the recognition of this term as a characterizing element of the composition claims would negate the asserted position that Applicant is using the recited components for the very "same function" as that of Singh. Applicants claim a viscoelastic composition. AB,

page 15, first paragraph. Specifically, a viscoelastic composition is required to “maintain the shape of a cavity during [surgical] operation including [such cavities as] the anterior chamber and the capsular bag” of the eye. To achieve this necessary function, the claimed composition must possess at least one of the viscosity values recited in claims 26, 27 and 47.

Again, these claims are rejected without sufficient reason. The recited range of shear-viscosities is dismissed as simply “known properties of a liquid composition, such that their determination would have been obvious to one of ordinary skill in the art using no more than routine examination where the primary reference [Singh] teaches the selection of gums is used to produce a proper viscosity.” EA, page 4. This is again legal error for at least two reasons.

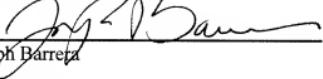
First, the Examiner selects hyaluronic acid from a list of twenty-three gums, and HPMC from a list of ten acceptable mucoadhesive polymers, listed in Singh. Moreover, there exists no particular preference for hyaluronic acid or for the addition of the optional mucoadhesive polymer. AB, pages 15-17. What teaching in Singh or any of the secondary references suggest that the Examiner’s proposed modification of Example ID21 would lead to a viscoelastic composition with the recited viscosities?

Second, Singh is concerned with the development of compositions for the delivery of a pharmacologically active agent to the eye. As Singh describes, a major problem with the administration of ophthalmic drugs is the “rapid and extensive precorneal loss caused by drainage and high tear fluid turnover.” A mixture of the gum polymers is said to increase the retention time of the active agent in the eye. More importantly, Singh does not describe ophthalmic compositions that can be used to maintain the shape of a cavity during [surgical] operation including [such cavities as] the anterior chamber and the capsular bag” of the eye. In fact, why would one of ordinary skill in the art seek to modify one of Singh’s compositions to

possess a shear-viscosity recited in the claims if that same person was concerned with a sustained delivery of an ophthalmic drug?

Reconsideration of this application is respectfully requested for the reasons stated.

Respectfully submitted,


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